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08/249,689	05/26/1994	PAUL R. SCHIMMEL	MIT5261	9517

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EXAMINER

BRUSCA, JOHN S

ART UNIT

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Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 08/249,689
Filing Date: May 26, 1994
Appellant(s): SCHIMMEL, PAUL R.

Paper No. 63
mailed 1/2/03

Patrea L. Pabst
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 09 December 2002.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

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(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect. The amendment after final rejection filed on 03 December 2002 as well as the amendment filed 05 July 2001 have been entered.

(5) *Summary of Invention*

The summary of invention contained in the brief is deficient because the paragraph bridging pages 2-3 discuss a process of making an inhibitor of ribonucleic acid function, while the claims on appeal are drawn to a product.

The summary of invention contained in the brief is deficient because on page 3 lines 11-13 of the brief the statement recites,

"The claimed compounds are defined by their function and by their structure, since they must be complementary to the critical site within the RNA to be inhibited."

Because the description of the claimed compounds is limited to a description of the function of the claimed compounds, the above statement is incorrect.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

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The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because:

1) Claim 13 is not accounted for in the groupings suggested by the appellant.

2) Reasons for distinctness between all three groups suggested by the appellant are not provided. It is further noted that no restriction requirement was made in this application between any of the originally filed process and product claims.

3) Suggested groups 1 and 2 differ only in limitations of the type of nucleic acid target that the claimed compound must bind. Suggested group 3 requires that the claimed compound is a nucleic acid. All suggested groups have been solely rejected for lack of written description of the claimed compound because the structure of the claimed compound cannot be determined from a reading of the specification by one of skill in the art. In the brief on page 18, lines 8, the reason proposed by the applicants for the claims not standing and falling together is apparently because each of the claims depending claim 11 contain a further limitation on the claimed compound or the target of the claimed compound. The additional limitations of claims 12, 13, and 17-19 do not provide a narrower description of the claimed compounds because the structural limitations of the target of the claimed compound result in functional rather than structural limitations of the claimed compound. The additional limitation of the claimed compound in claim 21 is that the claimed compound is a nucleic acid (potentially either RNA or DNA transcribed from a retroviral vector) which is a broad genus of compounds. The claimed subgenus of ribonucleic acid compounds in claim 21 is defined by functional rather than structural limitations. Because the structure of the compounds of suggested groups 2 and 3 are no

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more described than the compounds of suggested group 1, the claims should stand and fall together.

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claim 11-13, 17-19, and 21 are rejected under 35 U.S.C. 112, first paragraph. This rejection is set forth in prior Office Action, Paper No. 46.

(11) *Response to Argument*

The appellant states on page 5 of the brief that the invention is a pioneering invention, yet the appellant also states on page 5 and pages 19-21 that the claimed invention is analogous to that of an antibody and an antigen. The appellant states,

“One does not need to provide the exact nucleotide sequence encoding an antibody, or the exact structure of an antibody, in order to know what it is and how to use it. This is because the structure and function of an antibody is so well known.”

Satisfaction of the written description requirement for the claimed genus of compounds is not analogous to description of an antibody where the structure of the corresponding antigen is described because the instant claimed genus of compounds is novel and unobvious. Therefore one of skill in the art could not rely on structures of known related compounds to understand the structures of the claimed compounds as for the case of a antibody directed to a described structure of an antigen. The appellant state on pages 12-13 that a written description requirement

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may be met by showing “functional characteristics when coupled with a known or disclosed correlation between function and structure”. However in the instant specification there is no showing of a correlation between the claimed function of forming hydrogen bonds and structures of the claimed compounds. The appellant again states on pages 26-27 that the claimed invention is a pioneering invention. However the appellant do not provide persuasive arguments that pioneering inventions may meet a lower standard of compliance of the written description requirements of 35 U.S.C. § 112, first paragraph.

In pages 6-9 and pages 17-19 of the brief the appellant points to the limitation of claim 11 regarding the requirement of the claimed compounds to comprise hydrogen bond donor and acceptor sites arranged to specifically bind a critical region in the minor groove of a targeted RNA and inhibit the targeted RNA. The appellant states that the limitation is a structural limitation. However, claim 11 merely requires that the claimed compound performs the function of forming a hydrogen bond at the recited site. The limitation is a functional limitation and not a structural limitation. Whatever structural correlations might be inferred from the functional limitations of claim 11 end at the hydrogen bond. The claims comprise no limitation as to the structure of the compound that might form the hydrogen bonds, other than in claim 21 where the compound is limited to the genus of nucleic acids.

The appellant states that the claimed compounds fit the targeted ribonucleic acid like a “lock and key” at page 25. However the analogy is only partially correct. While there must be an overall complementarity of molecular shape between the claimed compounds and the targeted ribonucleic acid, shape at the molecular level is not equivalent to shape of macroscopic objects such as locks and keys. What may be termed shape at the molecular level of the claimed

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compounds is dominated by atomic and molecular properties such as van der Waals' forces, hydrogen bonding, hydrophobic bonding, ionic charges, and solvation by water. These shape related properties of the claimed molecules are insignificant to the shape of locks and keys. Adequate description of the claimed compounds requires a molecular structure that is not immediately apparent from the molecular structure of a targeted RNA molecule. Claim 11 also requires that the claimed compounds perform the function of inhibiting the activity of the target RNA molecule. Determination of critical regions of the target RNA that allow for inhibition may require empirical experimentation. Although it has been determined that one of skill in the art could make the claimed compounds, the structures of the compounds produced by the process required for making the claimed compounds has not been described in the instant specification.

On pages 9-11 of the brief the appellant rebuts a perceived rejection for lack of enablement, however the outstanding rejection is for lack of written description, which has been made clear in the Office actions mailed 30 April 2001, 11 January 2002, and the advisory action mailed 10 June 2002.

The appellant refers on page 10 of the brief to attachments. The attachments have not been considered because they are not filed as a separate paper, as required in MPEP 1207, and because the appellant has not provided a good and sufficient reason why they were not presented earlier as required by 37 CFR 1.195. The appellant appears to cite the attachments to rebut a perceived rejection for lack of enablement. The outstanding rejection is solely for lack of written description under 35 U.S.C. § 112, first paragraph.

The appellant discusses post filing art on pages 15-16 without demonstrating their relevance to written description of the claimed invention.

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The appellant states on page 21 of the brief that "a compound may also be claimed in terms of the process by which it is made without raising the issue of indefiniteness", however no product by process claims are on appeal, nor is there a rejection under 35 U.S.C. § 112, second paragraph on appeal.

The appellant alleges on page 26 of the brief that only independent claim 11 has been examined, however all claims on appeal have been rejected as lacking written description for the same reason. Neither rejected claims 11-13, 17-19, and 21, nor the specification contain a sufficient written description such that one of skill in the art would understand that the applicants had possession of the claimed compounds at the time of filing the instant application. None of the claims on appeal differ in scope sufficiently to adequately describe the claimed compounds. The narrowest claim is claim 21, which is limited to nucleic acid compounds, is drawn to a subgenus of the large genus of all nucleic acids without a further structural limitation. The functional limitations of all claims are equivalent. Absent an art recognized correlation at the time of filing between the claimed functional limitations and the structure of the claimed compounds the claimed subject matter is not described sufficiently to satisfy the requirements of 35 U.S.C. § 112, first paragraph.

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Respectfully submitted,

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December 23, 2002

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